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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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20306	7590	02/12/2009	EXAMINER	
MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP			MERTZ, PREMA MARIA	
300 S. WACKER DRIVE				
32ND FLOOR			ART UNIT	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/533,290	HOLTET ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 15 January 2009.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1, 18-23, 30 and 35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1, 18-23, 30, 35 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

**DETAILED ACTION**

1. Claims 2-17 have been cancelled previously.

Amended claim 35 (1/15/09) and previous claims 1, 18-23, 30, are pending and under consideration by the Examiner.

2. Receipt of applicant's arguments and amendments filed on 1/15/2009 is acknowledged.
3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 1/15/2009:
  - (i) the rejection of claims 35 under 35 U.S.C. 112, second paragraph.

Applicant's arguments with respect to claim 35 have been considered but are moot in view of the new ground(s) of rejection.

4. Applicant's arguments filed on 1/15/09 have been fully considered and were persuasive in part. The issues remaining and new issues are stated below.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim rejections-35 USC § 112, first paragraph, written description***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6a. Claims 1, 18-23, 30, 35, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

This rejection is maintained for reasons of record set forth at pages 2-6 of the previous Office action (8/22/2008).

Applicants argue that they respectfully disagree with the Action's assertion that the specification does not provide an adequate written description of the trimeric polypeptides of claim 1, to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention (*see M.P.E.P. § 2163*), an inventor can show possession by describing an actual reduction to practice of the claimed invention, by a clear depiction of the invention in detailed drawings or in structural chemical formulas, or by any description of sufficient, relevant, identifying characteristics (i.e., structure or other physical and/or chemical properties, functional characteristics coupled with a known or disclosed correlation between function and structure, or a combination of such identifying characteristics) (*id.*). Applicants also argue that claim 1 recites a trimeric polypeptide comprising three monomers, each of said monomers comprising a specific binding member capable of binding a trimeric cytokine, and each of said monomers comprising a trimerising domain that is derived from tetranectin and with respect to the portion of the claimed trimeric polypeptide that is a

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specific binding member capable of binding a trimeric cytokine, the specification defines a specific binding member as "a member of a pair of molecules which have binding specificity for one another" (¶ 27 of specification), and defines trimeric cytokines as being "small proteins and fragments thereof, which are produced and secreted by a cell, and which elicit a specific response in a cell which has a receptor for that cytokine, e.g. by affecting the growth, division and/or function of the cell" (¶ 24). However, contrary to Applicants arguments, except for a trimeric polypeptide comprising three monomers, wherein each monomer comprises the amino acid sequence set forth in SEQ ID NO:106 or SEQ ID NO:1077 or SEQ ID NO:108, and each monomer comprises a specific cytokine binding domain and a tetranectin trimerising domain wherein the tetranectin trimerising domain comprises the amino acid sequence of SEQ ID NO:81, Applicants have failed to provide a written description for any other trimeric polypeptide.

The instant specification does not provide an adequate description for the tetrameric polypeptide encompassed by claims 1, 18-20, 22, 23, 30, 35. In the decision of *The Regents of the University of California v. Eli Lilly and Company*, 43 USPQ2d 1398 (CAFC 1997), the court held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997), *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("(T)he description must clearly allow persons of ordinary skill in the art to recognize that (the inventor) invented what is claimed). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations,

not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

In the instant application, there is a complete lack of written description for the tetrameric polypeptide of claims 1, 18-20, 22, 23, 30, 35. The following decisions: *University of Rochester v. G.D. Searle & Co.*, 68 USPQ2d 1424 (DC WNY 2003) and *University of Rochester v. G.D. Searle & Co.*, CAFC (03-1304) decided February 13, 2004 and *Noelle v. Lederman*, decided January 20, 2004, are relevant to the instant rejection.

In *University of Rochester v. G.D. Searle & Co.*, a patent directed to method for inhibiting prostaglandin synthesis in human host using an unspecified compound, in order to relieve pain without side effect of stomach irritation, did not satisfy written description requirement of 35 U.S.C. §112, since the patent described the compound's desired function of reducing activity of enzyme PGHS-2 without adversely affecting PGHS-1 enzyme activity, but did not identify said compound, since the invention consisted of performing "assays" to screen compounds in order to discover those with desired effect. The patent did not name even one compound that assays would identify as suitable for practice of invention, or provide information such that one skilled in art could identify suitable compound. And since the specification did not indicate that the compounds were available in a public depository, the claimed treatment method could not be practiced without the compound. The written description requirement must still be met in some way so as to "describe the claimed invention so that one skilled in the art can recognize what is claimed." *Enzo*, 323 F.3d at 968. The Court further explained that:

[T]he appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. . . . A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its function of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice. [Regents of the Univ. of Cal. v. Eli Lilly [& Co., Inc.], 119 F.3d [1559,] 1568 [(Fed. Cir. 1997) (“Lilly”)] . . . . The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. Id.

*Enzo*, 323 F.3d at 968.

Thus, the Court in *University of Rochester* held that the inventors could not be said to have “possessed” the claimed invention without knowing of a compound or method certain to produce the compound. Thus, the patent constituted an invitation to experiment to first identify, then characterize, and then use a therapeutic a class of compounds defined only by their desired properties.

Therefore, similar to *University of Rochester*, here, the full breadth of the claims fails to meet the written description provision of 35 U.S.C. §112, first paragraph.

In the *Noelle* case, the claims in the Noelle application were directed to the genus, murine, chimeric, humanized and human forms of CD40CR monoclonal antibody. An interference was set up between the Noelle application and the Lederman patent 5,474,771, which claimed the human form of CD40CR monoclonal antibody. The Court concluded that the

Board made a detailed analysis of this court's precedent pertaining to the doctrine of written description, focusing on the holding from Regents of the University of California v. Eli Lilly & Co. that an "adequate written description of a DNA sequence claim requires a precise definition, such as structure, formula, chemical name, or physical properties." 119 F.3d 1559, 1566 (Fed. Cir. 1997). The Board analogized the DNA claims from Regents to the antibodies in Noelle's application. Accordingly, the Board held that Noelle's claims regarding the genus and human claims from the 08/742,480 application lacked written description support in the specification of Noelle's earlier 07/835,799 application because Noelle failed to describe any structural features of the human or genus antibodies or antigens. In other words, the Board found that the claims covering the genus and human antibodies constituted new matter because they lacked adequate written description in Noelle's earlier '799 application. The Board did not reject the claims, but rather denied them the benefit of the earlier filing date of Noelle '799.

The Court in Noelle held that the written description requirement has been defined many times by the court, but perhaps most clearly in Vas-Cath. The court held as follows:

35 U.S.C. § 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed.

Vas-Cath, 935 F.2d at 1563-64 (emphasis in original). Thus, the test to determine if an application is to receive the benefit of an earlier filed application is whether a person of ordinary skill in the art would recognize that the applicant possessed what is claimed in the later filed application as of the filing date of the earlier filed application. An earlier application that describes later-claimed genetic material only by a statement of function or result may be insufficient to meet the written description requirement. See Regents, 119 F.3d at 1566. This court has held that a description of DNA “requires a precise definition, such as by structure, formula, chemical name, or physical properties,’ not a mere wish or plan for obtaining the claimed chemical invention.” Id. (quoting Fiers v. Revel, 984 F.2d 1164, 1170 (Fed. Cir. 1993)). Therefore, this court has held that statements in the specification describing the functional characteristics of a DNA molecule or methods of its isolation do not adequately describe a particular claimed DNA sequence. Instead “an adequate written description of DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself.” Id. at 1566-67 (quoting Fiers, 984 F.2d at 1171).

Indeed, the court in Enzo Biochem v. Gen-Probe, Inc., 323 F.3d 956, 964 (Fed. Cir. 2002) (“Enzo Biochem II”), stated that “the written description requirement would be met for all of the claims [of the patent at issue] if the functional characteristic of [the claimed invention was] coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed.” Also, the court held that one might comply with the written description requirement by depositing the biological material with a public depository such as the American

Type Culture Collection (“ATCC”). Id. at 970. The court proffered an example of an invention successfully described by its functional characteristics. The court stated:

For example, the PTO would find compliance with 112, paragraph 1, for a claim to an isolated antibody capable of binding to antigen X, notwithstanding the functional definition of the antibody, in light of the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature.

Id. The court adopted the USPTO Guidelines as persuasive authority for the proposition that a claim directed to “any antibody, which is capable of binding to antigen X” would have sufficient support in a written description that disclosed “fully characterized antigens.” Synopsis of Application of Written Description Guidelines, at 60, available at <http://www.uspto.gov/web/menu/written.pdf> (last visited Jan. 16, 2003) (emphasis added).

Therefore, based on past precedent, the Court in *Noelle* concluded that as long as an applicant has disclosed a “fully characterized antigen,” either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen.

Therefore, the CAFC decisions in *Noelle* and *University of Rochester* are controlling precedents for the claims in the instant case and it is suggested that Applicant visit these decisions. There is absolutely no written description for the claimed subject matter drawn to a

trimeric polypeptide as recited in claim 1. Therefore, Applicants were not in possession of the claimed trimeric polypeptides.

Applicants also argue that the human TTSE is 36 amino acids and 15 amino acids are conserved in human and murine tetranectin. However contrary to Applicants arguments, there are more amino acids between human TTSE and murine TTSE that are not conserved compared to those that are conserved. Therefore, other than the tetranectin trimerising domain set forth in SEQ ID NO:81, Applicants have failed to provide an adequate written description of the trimeric polypeptides of claims 1, 18-19. To provide adequate written description and evidence of possession of the claimed polypeptides, the specification must provide sufficient distinguishing identifying characteristics of the genus of trimeric polypeptides. In this case, the specification does not identify other monomers in the trimeric polypeptide other than SEQ ID NO:106, 107 and 108. The distinguishing characteristics of the claimed genus of trimeric polypeptides has not been described. Applicant cannot lay claim to subject matter unless he can provide a description of the claimed subject matter. Accordingly, the specification does not provide adequate written description of the claimed trimeric polypeptides.

***Claim Rejections - 35 U.S.C. § 112, first paragraph, scope of enablement***

6b. Claims 1, 18-23, 30, 35, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a trimeric polypeptide comprising three monomers, wherein each monomer comprises the amino acid sequence set forth in SEQ ID NO:106 or SEQ ID NO:7 or SEQ ID NO:8, and each monomer comprises a specific cytokine binding domain and a tetranectin trimerising domain wherein the tetranectin trimerising domain comprises the amino

acid sequence of SEQ ID NO:81, does not reasonably provide enablement for as recited in claims 1, 18 and 19. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection is maintained for reasons of record set forth at pages 7-9 of the previous Office action (8/22/2008).

Applicants argue that the specification provides enablement for the genus of trimeric polypeptides recited in claims 1, 18, and 19, and as described in section 2(a) above, the specification contains substantial teachings about the portion of the claimed trimeric polypeptide that is a specific binding member capable of binding a trimeric cytokine, and further, states that the trimerising domain that is derived from tetranectin of the claimed trimeric polypeptides comprises a tetranectin trimerising structural element (also called TTSE), which is described in detail in International Publication No. WO 98/56906 (the '906 publication) and therefore, one of ordinary skill in the art would therefore readily recognize how to make and use the claimed trimeric polypeptides of the instant invention. However, contrary to Applicants arguments, the issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. This position is consistent with the decisions in In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) and Amgen Inc. V. Chugai Pharmaceuticals Co. Ltd., 13 USPQ2d, 1737 (1990), and In re Wands, 8USPQ2d, 1400 (CAFC 1988) (which has been cited by Applicants. If Applicants will kindly review page 1404 of In re Wands, they will find that the factors to be considered in determining whether a disclosure would

require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims. Applicants arguments that the standard is that of obtaining a subject turmeric polypeptide that has a portion which is a specific binding member capable of binding a trimeric cytokine, and testing to see if it retains the desired biological activity is a position that has been routinely dismissed by the courts, as shown by the decisions cited above.

Further, In re Wands determined that the repetition of work which was disclosed in a patent application as producing a composition containing an antibody, which is a naturally-occurring compound, did not constitute undue experimentation even if the antibody produced thereby was not identical to those that were disclosed in that application. The instant claims are not limited to naturally-occurring compounds and the instant specification does not provide a description of a repeatable process of producing the claimed trimeric polypeptide whose tetranectin trimerising domain amino acid sequence deviates from the disclosed sequence by as much as 17%. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve the determination of those amino acid residues which are required for functional and structural integrity of those proteins. It is this additional characterization of the disclosed protein that is required in order to obtain the functional and structural data needed to permit one to produce a

trimeric protein which meets both the structural and functional requirements of the instant claims that constitutes undue experimentation.

Furthermore, Applicant is encouraged to review the discussion of 35 U.S.C. § 112, first paragraph, in a recent CAFC decision, Genentech, Inc. v. Novo. Nordisk, 42 USPQ2d, 100 (CAFC 1997), in which the decisions in In re Fisher, Amgen Inc. V. Chugai Pharmaceuticals Co. Ltd., and In re Wands were considered as the controlling precedents in determining enablement issues where protein and recombinant DNA issues are concerned. These decisions have been relied upon in the instant rejection and by the Court because they show that the judicial interpretation of the first paragraph of 35 U.S.C. § 112 requires that the breadth of claims must be based upon the predictability of the claimed subject matter and not on some standard of trial and error. To argue that one can make material embodiments of the invention and then test for those that work in the manner disclosed or that the instant claims only encompass the working embodiments is judicially unsound. Unless one has a reasonable expectation that any one material embodiment of the claimed invention would be more likely than not to function in the manner disclosed or the instant specification provides sufficient guidance to permit one to identify those embodiments which are more likely to work than not, without actually making and testing them, then the instant application does not support the breadth of the claims. In the instant case it is highly improbable that a trimeric protein having a tetranectin trimerising domain with amino acid sequence identity of 87% or 92% identity to that disclosed in SEQ ID NO:81 will more likely than not perform in the manner disclosed and the instant specification does not provide the guidance needed to predictably alter the sequence with any reasonable expectation that the resulting protein will have the desirable activity.

***Claim rejections-35 U.S.C. 112, second paragraph***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 21, 35, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21, line 2, is vague and indefinite because it recites “SEQ ID NO:106 SEQ ID NO:108” rather than the correct “SEQ ID NO:106, SEQ ID NO:108”.

Claim 35, line 3, is vague and indefinite because it recites “substituted with to...” rather than the correct “substituted with”.

***Claim rejections-Double Patenting***

***Non-statutory double patenting rejection (obviousness-type)***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8a. Claims 1, 18-20, 30, are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 56-68 of copending Application No. 11/452,434 ('434). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 56-64, 80-81 of copending Application No. 11/452,434 (having one common inventor with the instant application), claims a trimeric polypeptide complex comprising three monomer polypeptides, wherein (i) each of said monomer polypeptides comprises a tetranectin trimerising structural element (TTSE), said TTSE being a polypeptide having at least 68% amino acid sequence identity with the consensus sequence shown in SEQ ID NO:40 and (ii) at least one of said monomer polypeptides is covalently linked to at least one heterologous moiety, where said at least one heterologous moiety is different from any of the fusion proteins CIIH6FXTN123, H6FXTN123, H6FXTN12, H6FCTN23, the sequences of which are shown in SEQ ID NOs:24-27, and said complex remains as a trimer at a temperature of at least 60°C.

This rejection is maintained for reasons of record set forth at pages 9-11 of the previous Office action (8/22/2008).

Applicants argue that they acknowledge the provisional rejection under the doctrine of obviousness-type double patenting, and elect to address this ground of rejection upon notification that this rejection has been made non-provisional, all other conditions for patentability have been met, and the instant claims are otherwise in condition for allowance. However, contrary to Applicants arguments, the instant claims will never be allowable unless a terminal disclaimer is filed to obviate the provisional nonstatutory obviousness-type double patenting rejection.

***Conclusion***

No claim is allowed.

Claims 1, 18-23, 30, 35, are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Prema Mertz/  
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Primary Examiner  
Art Unit 1646